

REMARKS

This paper is responsive to the Office Action of January 24, 2008. In the Office Action the Examiner withdrew the final rejections entered previously in view of new grounds of rejection presented in the action.

Claims 29, 32, 34, 35 and 37 were rejected under 35 U.S.C. §102(b) as being anticipated by Fuqua (USP 4,710,181). Claims 46, 47, 50 and 51 were rejected under 35 U.S.C. §102(b) as being anticipated by Schreck (USP 4,411,655). Claim 36 was rejected under 35 U.S.C. §103(a) as being unpatentable over Fuqua. Claims 31, 33, 38, 40, 48 and 49 were objected to as being dependent upon a rejected base claim, but were indicated as allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Section 102(b) rejections.

Claims 29, 32, 34, 35 and 37:

As stated above, claims 29, 32, 34, 35 and 37 were rejected under 35 U.S.C. §102(b) as being anticipated by Fuqua. Fuqua is directed to a variable diameter catheter 10 which is folded in a longitudinal manner in order to reduce the diameter for less traumatic insertion into a body orifice. A longitudinal fold 15 in the catheter is maintained by a slidably removable external sheath 60 which aids in insertion of the catheter and in dispersion of an anti-infective medication. After the catheter is placed in the body orifice, the external sheath is removed, and the catheter expands to its full size. Col. 5, lines 20-27.

Claim 29 has been amended as illustrated above. As amended, the insertion member is specified as being receivable within the axial opening of the sheath body for holding said folded distal portion of said sheath body in said non-expanded condition. In Fuqua, the element (sheath 60) identified by the Examiner as meeting the limitation of the insertion member is not receivable within the axial opening of sheath body 14, but rather, envelopes the sheath body. Thus, Fuqua does not

anticipate claim 29, as amended.

In addition to the foregoing, Applicants have incorporated the limitation originally presented in claim 31 that the insertion member comprises a cannula having an inner lumen, and that the folded distal portion of the sheath body is folded within the inner lumen. Fuqua also does not teach this limitation, and therefore, does not anticipate amended claim 29 for at least this additional reason. Applicants note that claim 31 was objected to in the Office Action, but indicated as allowable if rewritten in independent form. Although Applicants did not incorporate all of the limitations of claim 31 into claim 29, it is believed that the limitations so incorporated are neither taught nor suggested in Fuqua.

Claims 30-38 and 40 depend, directly or indirectly, from claim 29, and are also allowable for at least the same reasons that claim 29 is allowable. In addition to the foregoing, Applicants take particular issue with the Examiner's contention that the limitation in claim 37 of an axial slit extending substantially along the length of the sheath body is met by Fuqua. According to the Examiner, this limitation is met by folded portion 15 extending along the length of the sheath body in the non-expanded condition. As stated in the present application, the axial slit comprises a weakened portion, such as portion 23, in the sheath body. The sheath body is splittable along this weakened portion for facilitating removal of the sheath after insertion of the medical device therethrough. See, e.g., application, page 6, lines 19-21. Applicants dispute that the limitation of a slit is met by the fold of Fuqua, and further dispute that a skilled artisan would consider the fold of Fuqua as an axial slit.

Claims 46, 47, 50 and 51:

Claims 46, 47, 50 and 51 were rejected under 35 U.S.C. §102(b) as being anticipated by Schreck. Schreck is directed to an apparatus for percutaneous catheterization of a vessel or like structure. The apparatus employs a shape memory alloy cylindrical cannula which diametrically expands after introduction into the

vessel with sufficient radial force to dilate the vessel. A cylindrical sheath embracing the cannula facilitates introduction and insulates the vessel from contact with the metal of the cannula.

As a preliminary matter, Applicants state that it appears that the Examiner has combined elements from the two separate embodiments of Schreck in order to support the rejection. Applicants respectfully submit that it is improper to pick and choose elements from different embodiments in order to satisfy the criteria of 102(b), but rather, that the "invention" should be described in a single structure.

Claim 46 has been amended as indicated above. As amended, the insertion cannula is specified as being receivable within the axial opening of the sheath body. In Schreck, the element (hub 6) identified by the Examiner as meeting the limitation of the insertion cannula is not receivable within the axial opening of sheath body 44. Rather, it envelopes the proximal end of the sheath body. Thus, Schreck does not anticipate claim 46, as amended.

In addition, Applicants dispute that other limitations are met by the Schreck disclosure. For example, the Examiner contends that the limitation of the dilator is met by needle 3. Applicants respectfully submit that a needle and a dilator are each well-known features of medical devices in widespread use in the medical community. Each device has its particular purpose, e.g., a needle for making an initial puncture, and a dilator for controllably stretching that puncture to facilitate introduction of a medical device. A skilled artisan would not read a publication that makes reference to a needle, and equate this structure with a dilator, as taught in the present application.

Claims 47-53 depend, directly or indirectly, from claim 46, and are also allowable for at least the same reasons that claim 46 is allowable.

Section 103(a) rejection.

Claim 36 was rejected under 35 U.S.C. §103(a) as being unpatentable over

Fuqua. As stated above. Claim 36 depends from claim 29, and therefore includes all of its limitations, including the limitations specifically recited in the discussion of claim 29 above related to the position of the insertion member, and the placement of the folded distal portion of the sheath body. Neither of these limitations is taught or suggested in Fuqua. Therefore, Applicants respectfully submit that claim 36 is not obvious in view of Fuqua.

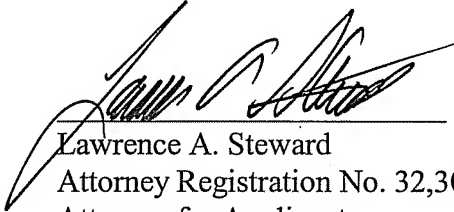
Claim Objections.

Claim 36 was objected to due to an informality. The claim has been corrected in accordance with the suggestion provided by the Examiner in the Office Action. Applicants appreciate the Examiner pointing out this informality.

Conclusion:

Based upon the foregoing, Applicants respectfully submit that the rejections to the claims have been overcome and that all claims 29-38, 40 and 46-53 are in condition for allowance. Accordingly, Applicants request the prompt issuance of a Notice of Allowance. If the Examiner believes that any minor issues remain for resolution prior to issuance of the Notice of Allowance, the Examiner is respectfully invited to telephone the undersigned attorney in order to expedite prosecution.

Respectfully submitted,



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